

# **R & S SALES, INC.**

FAX  
270-434-2880

8407 AUSTIN TRACY RD.  
FOUNTAIN RUN, KY 42133  
PHONE  
270-434-2045

TOLL FREE  
800-626-0208

June 29, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

Dear Sir/Madam:

Re: Docket Nos. 92N-0297 and 88N-0258

We are licensed prescription drug wholesalers doing business in 35 states. While we purchase some of our inventory through two of the major full-line wholesale distributors, we purchase approximately 70 percent of our inventory from smaller wholesale distributors who, in some cases, are not authorized distributors for the products they sell. We also purchase directly from about 40 drug companies. We have tried to become authorized distributors with manufacturers but our requests have been turned down or simply ignored.

We do not receive prescription drug pedigrees from full-line wholesalers or from manufacturers. If we were required to provide prescription drug pedigrees that go back to the manufacturer to our customers, we could do so only in those instances where we have purchased directly from the manufacturer or purchased from an "unauthorized distributor" who is able to provide that complete information to us. However, those "unauthorized distributors" will not be able to do so unless they purchased directly from the manufacturer, which is rarely the case. Since we do some of our business with major full-line wholesalers who do not provide any pedigrees, and because most "unauthorized distributors" will not be able to provide pedigrees back to the manufacturer, we will not be able lawfully to engage in 70 percent of the transactions we now engage in.

Our company services over 500 retailers/physicians/clinics and other customers. All of these customers will be adversely affected if we are not able to supply them. Our company employs over 50 people who will be put out of their jobs if the prescription drug pedigree requires that transactions be reported back to the manufacturer.

88N-0258

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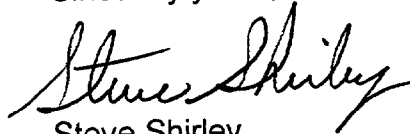
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We support a return to the guidance issued by FDA in August 1988 with respect to prescription drug pedigrees and authorized distributors.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Steve Shirley".

Steve Shirley  
President